

235.35**Infant Formula Overview****Definitions****Introduction**

This policy defines the categories of infant formula.

Definition of infant formula

Infant formula means a food that meets the definition of an infant formula in section 201(z) of the Federal Food, Drug, and Cosmetic Act (21 USC 321(z)) and that meets the requirements for an infant formula under section 412 of the Federal Food, Drug, and Cosmetic Act (21 USC 350a) and the regulations at 21 CFR parts 106-107.

Issuance of formulas

Local agencies must issue as the first choice of issuance the primary contract brand infant formula to the majority of healthy full-term infants.

Categories

The categories of infant formulas and their definitions are listed below.

Category	Definition	Examples
Primary contract formula	The specific infant formula for which manufacturers submit a bid to the State Agency in response to a rebate solicitation and for which a contract was awarded by the State Agency as a result of that bid	Similac Advance Stage 1 Similac for Spit Up Similac Sensitive Similac Soy Isomil Similac Total Comfort
Exempt	An infant formula that is represented and labeled for use by infants who have inborn errors of metabolism or low birth weight, or who otherwise have unusual medical or dietary problems	Similac Expert Care Alimentum Nutramigen Pregestimil Neocate Infant Formulas for inborn errors of metabolism Premature formulas

Category	Definition	Examples
Non-Contract	All infant formulas, including exempt infant formula, that are not covered in the current infant formula cost containment contract	Enfamil A.R. Enfamil Premium Infant Enfamil Gentlease Gerber Good Start Soy Enfamil ProSobee Private label infant formulas

Policy references

- WC-04-34-P: Implementation of the Infant Formula Cost Containment Provisions of Public Law 108-265
- WIC Policy Memorandum #2014-1 Changes to Abbott Infant Formula Product Line
- WIC Policy Memorandum #2014-1A Clarification on Medical Documentation for Infant Formula Issued in Food Packages I and II